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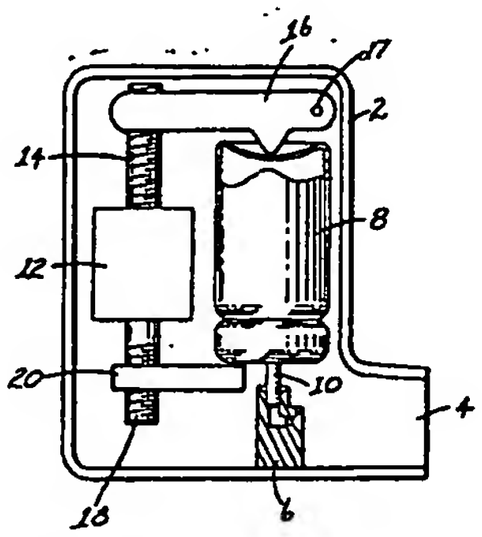

(57) Abstract

An inhalation device for use with a pressurised aerosol canister containing a self-propelling medicament composition equipped with a dispensing valve having a stem moveable relative to the canister between a closed position and a dispensing position, the device comprising a housing for supporting said canister and maintaining the valve stem in a fixed position relative to said housing in communication with a patient port, the device additionally comprising electromechanical means for moving said canister thereby actuating the dispensing valve for administration of medicament.

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INHALER

This invention relates to dispensers for use with aerosol containers which contain medicaments for inhalation therapy, are pressurised with liquid propellants, and include a metering valve through which a series of metered medicament doses can be dispensed.

Inhalation activatable dispensers for use with aerosol container assemblies of the type described above are known, their general purpose being to afford proper co-ordination of the dispensing of a dose of medicament with the inhalation of the patient thereby allowing the maximum proportion of the dose of medicament to be drawn into the patient's bronchial passages. Examples of such dispensers are described in British Patent Specification Nos. 1,269,554, 1,335,378, 1,392,192 and 2,061,116 and United States Patent Nos. 3,456,644, 3,456,645, 3,456,646, 3,565,070, 3,598,294, 3,814,297, 3,605,738, 3,732,864, 3,636,949, 3,789,843 and 3,187,748 and German Patent No. 3,040,641.

European Patent No. 147028 discloses an inhalation activatable dispenser for use with an aerosol container in which a latch mechanism releasing vane is pivotally mounted in an air passage between an aerosol outlet valve and a mouthpiece, which latch mechanism cannot be released if force to activate the dispenser is not applied before a patient inhales.

The dispenser generally comprises a housing having a mouthpiece and an air passage therethrough terminating at the mouthpiece, the housing being adapted to receive an aerosol container, said dispenser having a support block with a socket adapted to receive the stem of the valve of the aerosol container and a through orifice communicating between the socket and the air passage, and latch means having parts movable between an engaged position in which

movement of the container and the support block toward each other upon the application of a force to bias the container and the support block toward each other is prevented and a release position in which movement of the container and the support block toward each other in response to said force is permitted causing the stem to move to its inner discharge position, the latch means comprising a vane mounted in the housing in the air passageway between the orifice and the mouthpiece for movement toward the mouthpiece under the influence of inhalation through the mouthpiece to release the latch means in which the vane moves toward the mouthpiece from a blocking to a non-blocking position with respect to the passageway in response to inhaling at the mouthpiece and releases the latch means only during the application of said force to bias the container and support block toward each other.

This inhalation device has been received favourably by patients and doctors since it not only overcomes the hand-lung co-ordination problem but it does so at a very low triggering flow-rate (approximately 30 litres/minute) essentially silently, and with a very compact design barely larger than a standard inhaler. It is necessary to manually prime the inhalation device with a lever to apply the bias to the container prior to use.

U.S. Patent No. 4,648,393 discloses an electrically-operated metered-dose inhaler in which a mechanical valve blocking means is withdrawn by the action of a solenoid moving in response to the closing of a switch; the switch constitutes an electromechanical breath-actuation means which responds to inhalation by the patient. The disclosed device relies entirely upon mechanical priming of the device by application of force to a spring.

WO87/04354 discloses a medical dosing device for the discharge of medicament for inhalation which comprises a

handheld holder for a medicine container from which medicine is discharged via a valve into an air channel for inhalation controlled by operation of an activation device. The valve is operationally connected with a control unit arranged on initiation of the activation device to control the discharge valve for intermittant opening and closing repeatedly within an inhalation period. The control unit is an electronically controlled unit which activates an electrically controlled discharge valve.

It is an object of the present invention to provide an inhalation device for use with a pressurised aerosol container equipped with a metered dose dispensing valve which does not require manual actuation for firing the valve.

Therefore according to the present invention there is provided an inhalation device for use with a pressurised aerosol canister containing a self-propelling medicament composition equipped with a dispensing valve having a stem movable relative to the canister between a closed position and a dispensing position, the device comprising a housing for supporting said canister and maintaining the valve stem in a fixed position relative to said housing in communication with a patient port, the device additionally comprising electromechanical means for moving said canister thereby actuating the dispensing valve for administration of medicament.

The invention provides an inhalation device which removes the need for the patient to manually actuate the aerosol valve by utilising electromechanical means, e.g., an electric motor or solenoid, to apply the required load for valve actuation to the aerosol canister or its associated valve ferrule. The provision of electromechanical means of valve actuation constitutes a

significant benefit for those patients, generally children, the elderly and infirm, who may experience difficulty in manually firing an aerosol valve. A conventional aerosol valve generally requires a force of from 18 to 35N to effect actuation. In a preferred embodiment of the invention the electromechanical means is associated with breath detection means such that the aerosol valve is actuated automatically during inhalation by the patient, thereby overcoming any problems associated with patient hand-lung co-ordination.

The electromechanical means actuates the aerosol valve by applying a load either directly or indirectly to the aerosol canister or its associated valve ferrule whilst the valve stem is held stationary. Applying the load to the canister in this way, rather than to the valve stem, has the important advantage of keeping the support block which houses the spray exit orifice stationary thereby obviating the need to move the mouthpiece in unison with the support block during actuation to ensure that the medicament is always dispensed to the same area in the mouthpiece and that dosage reproducibility is efficient.

An electric motor may be used to apply the load to the canister by numerous different arrangements. For example, the motor may drive through a worm gear attached to a threaded component which acts directly on the base of the aerosol canister. Actuation of the motor in one direction causes advance of the threaded component moving the aerosol canister to actuate the valve. In other embodiments of the invention one or more intermediate linkages are provided to achieve greater mechanical advantage. For example, a lever which is driven via a worm gear, a cam or suitable gear train may be utilised to apply the load to the canister.

Alternatively, the electromechanical means may be in the form of a solenoid which may be used to apply load directly to the aerosol canister or via an intermediate linkage to provide mechanical advantage in a similar manner to the linkages associated with an electric motor.

After actuation of the valve, the valve must be reset by returning the canister to its original position. The valve may be reset by returning the electromechanical means to its original position and allowing the aerosol canister to move under the influence of an internal spring within the valve, which is conventionally incorporated in all commercially available metered dose aerosol valves. In one embodiment of the invention the dispenser additionally comprises means for subsequently resetting the valve which may be operated by an electric motor or solenoid to drive the aerosol canister back to its rest position. The motor or solenoid may conveniently be the same as that used for valve actuation. The use of such reset means reduces the dependance upon the internal spring within the aerosol valve and accordingly the valve may be provided with an internal spring of reduced strength, compared to those conventionally employed, such that it need only be strong enough to return the aerosol valve to the reset position after pressure filling or function testing of the aerosol vial during manufacture. The strength of the valve spring is preferably selected so that a force of no greater than about 15N is required to effect actuation of the device compared with a force of from 18 to 35N for conventional aerosol valves. Reducing the strength of the valve spring reduces the force required to actuate the valve and, in turn, reduces the power requirements of the motor or solenoid and the power and energy requirements of the associated battery. Thus, the use of

valves having weak valve springs is a significant advantage in the design of pressurised inhalers having electromagnetic valve actuation and reset. The use of valves having weak springs and being reset by an electric motor or solenoid requires the valve stem to be held in position in the nozzle block.

Preferred inhalation devices in accordance with the invention additionally comprise means for detecting inspiration through the patient port associated with control means for actuating the device on detecting of inspiration. Such a breath actuation means may comprise a simple pivoted vane which moves to close an electric switch when the patient inhales through the patient port or may comprise other means for detection of inhalation, e.g., based upon change in temperature or pressure which provides a signal used to initiate activation of the electromechanical means to activate the valve. Other suitable means for detection of inhalation include flow sensors e.g. those which measure the speed of rotation of a turbine in the air stream.

Suitable inhalation devices are disclosed in our co-pending British Patent Application of even date entitled "Inhalation Device" and comprise a portable inhalation device for administration of medicament in the form of aerosolised fine particles or droplets of liquid or suspension to the respiratory system of a patient, the device comprising a housing defining a chamber in communication with a patient port in the form of a mouthpiece or nasal adaptor, medicament aerosolisation means for forming an aerosol of medicament in the chamber, control means to actuate the medicament aerosolisation means and a sensor which measures the air flow rate during respiration through the patient port and provides an electrical signal to the control means which

varies continuously with said flow rate, said electrical signal being used by the control means for one or more of the following functions:

(i) to calibrate the device such that the medicament aerosolisation means is actuated at a precise, pre-determined flow rate,

(ii) to monitor one or more of the following parameters:

(a) flow rate at different times during respiration,

(b) rate of change of flow rate during respiration,

(c) respired volume during respiration,

and activate the medicament aerosolisation means when a pre-determined inspiration parameter is attained.

The electromechanical breath actuated inhalers of the invention eliminate the need for manual actuation or priming of the device and avoid the need for a blocking mechanism to prevent firing of the valve which are required in devices where the mechanism is primed prior to breath actuation. In the devices of the invention, upon detection of the start of inhalation, or the attainment of some inhalation parameter, the motor or solenoid is energised and the load immediately applied to the aerosol canister causing the aerosol valve to fire.

The inhalation device of the invention may also include other electronic control features, e.g., to provide an indication of the number of doses dispensed or remaining, or to control the dosage frequency. For example, the device may include electronic control means such that the aerosol valve cannot be fired for a pre-determined period of time after a dose has been dispensed in order to ensure the patient does not take a further dose before the initial dose has had time to take effect. The control means may also prevent dispensing from the

device if the patient has received the maximum number of doses within a pre-determined period of time in order to prevent patient overdose. In addition, the control means may also prevent further dispensing from the device when a predetermined number of doses indicated on a label have already been taken, thus preventing "tail off" problems leading to reduced doses of medicament being dispensed. Since the electromechanical means would only be energised upon demand if so directed by the electronic control means the possibility of valve actuation when not permitted may be completely eliminated by ensuring the canister base and other internal components are inaccessible, thereby preventing unauthorised patient tampering etc.

The electronic control means may also control the valve resetting to ensure that the valve is reset under optimum conditions. Ideally, the valve should be reset immediately or shortly after valve actuation to ensure the device is set ready for the next use. Such immediate resetting greatly reduces or eliminates the possibility of vapour-lock formation in the valve which can occur if the valve is left in its fired state for a significant length of time or is allowed to reset when the aerosol container is not held in the upright position. In addition, the control means for valve resetting may include a tilt-detection means which provides a warning to the patient to hold the container vertically in order to prevent a vapour-lock occurring if the valve is reset when the aerosol canister is tilted and the liquid medicament therein is not in contact with the valve.

The invention will now be described with reference to the accompanying drawings in which:

Figures 1 to 8 represent schematic diagrams of inhalation devices in accordance with the invention and,

Figures 9 and 10 represent side and front sections respectively through an inhalation device in accordance with the invention.

Each of Figures 1 to 8 illustrate an inhalation device comprising a housing (2) having a patient port (4) in the form of a mouthpiece. The device comprises a nozzle block (6) which is fixed relative to the mouthpiece. A pressurised aerosol vial comprising an aerosol canister (8) equipped with a valve having a valve stem (10) is enclosed within the housing and arranged such that the valve stem (10) is firmly secured within the nozzle block (6). Movement of the aerosol canister (8) in the downward direction causes actuation of the valve dispensing medicament through the nozzle block (6) into the mouthpiece (4) for inhalation by the patient.

In any of the inhalers shown in Figures 1, 2, 3, 4 and 5 the motor could have associated with it a gearbox.

Referring to Figure 1 the electromechanical means for moving the aerosol canister (8) to fire the valve comprises a motor (12) attached to the housing (2) to prevent rotation which rotates a screw thread (14) passing through a threaded aperture on actuation lever (16). Activation of the motor rotates the screw thread (14) causing the actuation lever (16) to move downwards thereby moving the aerosol canister (8) and firing the valve (4). Vertical translational motion of the actuation lever (16) is ensured by two lugs (17), only one of which is shown, which engage complimentary vertical slots (not shown) in the wall of housing (2) thereby preventing rotation in any plane.

The device additionally comprises a second screw thread (18) passing through a threaded aperture on a valve reset arm (20) extending beneath the valve ferrule. When the motor is actuated to fire the valve the screw (18) is rotated causing downward movement of the reset

arm (20) to allow movement of the aerosol canister (8). Rotation of reset arm (20) is similarly prevented by two interengaging lugs/slots (not shown). When the valve is reset the motor is rotated in the opposite direction causing actuation lever (16) to return to its rest position and the reset arm (20) is raised with the aerosol canister (8) upwardly to its rest position.

The device may be actuated by manual pressing of a button (not shown) or by electrical inhalation detection circuitry (not shown). Actuation of the reset cycle may be initiated by manual pressing of a reset button, by electrical detection means which detects the cessation of patient inspiration, by a switch actuated on replacement or closing of a mouthpiece cover or after a preset time delay following actuation of the valve or immediately after the device has fired, or a combination of the above (e.g. preset delay after cessation).

The electromechanical means for moving the canister of the device shown in Figure 2 comprises a motor (22) attached to the housing (2) to prevent rotation which drives a screw (24) associated with a combined actuation driver (26) and reset arm (28). During actuation rotation of the screw (24) causes the actuation driver (26) to move downwardly causing corresponding movement of the aerosol canister to fire the valve. Rotation of the combined actuation driver/reset arm is prevented by lugs (29) which engage complimentary vertical slots or grooves in the wall of the housing. The reset arm (28) moves with the actuation driver and the valve is reset by driving the motor in reverse. Actuation of the valve and reset may be initiated by similar means to those discussed with reference to Figure 1.

With reference to Figure 3, the electromechanical means for moving the aerosol canister comprises a motor (30) attached to the housing (2) to prevent rotation which drives a screw (32) associated with a combined actuation driver (34) and reset arm (36) which are positioned either side of the valve ferrule (38) and are prevented from rotating with the screw. When the motor is activated to rotate the screw (32) the actuation driver (34) and reset arm (36) move downwardly causing movement of the aerosol canister (8) to fire the valve. The motor is then driven in reverse, returning the actuation driver and reset arm to the rest position causing upward movement of the canister (8) to reset the valve. Alternatively, the reset arm (36) may be eliminated, both valve actuation and reset being performed by driver (34). Actuation of the firing and resetting cycles of the valve may be arranged as discussed with reference to Figure 1.

Referring to Figure 4, the electromechanical means for moving the canister is similar to that shown in Figure 3 and comprises a motor (40), screw (42), actuation driver (44) acting on the valve ferrule (48) and a reset lever (46) which is connected to the actuation driver (44) at pivot (47). Two lugs (45) are provided to prevent rotation of the actuation driver (44) as described above for the device shown in Figure 1. The valve firing and resetting cycles operate as described with reference to Figure 3.

The electromechanical means for moving the aerosol canister in the device shown in Figure 5 comprises a motor (50) having a shaft (52) which is attached to a cam (54). The surface of the cam (54) acts on actuation driver (56) such that when the cam is rotated the actuation driver is caused to move downwardly, in turn causing down movement of the aerosol canister (8) to fire

the valve. Stop (57) on the cam and stop (58) on the actuation driver are provided to halt rotation of the cam when the required movement of the aerosol canister has been completed. Alternatively, a stepper motor could be used, thereby possibly obviating the need for a separate de-energising switch. The stops may act as a switch to de-energise the motor. The valve reset is achieved by driving the motor in reverse and either moving the canister upwards or allowing the aerosol canister to move upwardly under the influence of the internal spring of the aerosol valve.

Referring to Figure 6 the electromechanical means for moving the aerosol canister (8) comprises a solenoid (60) and a plunger (62) connected to a combined actuation driver (64) and reset arm (66) which act on either side of the valve ferrule (67). When the solenoid is energised the plunger moves downwardly causing downward movement of the actuation driver, valve reset arm and aerosol canister causing the valve to fire. The solenoid is de-energised and the plunger returns to its rest position under the influence of the solenoid return spring causing upward movement of the actuation driver, valve reset arm and aerosol canister to its rest position. Alternatively, the reset arm (66) may be eliminated, both valve actuation and reset being performed by driver (64). The firing and reset cycles of the valve may be initiated in the manner described with reference to the device illustrated in Figure 1.

Referring to Figure 7, the electromechanical means for moving the aerosol canister (8) comprises a solenoid (70) having a plunger (72) connected to an actuation arm (74) at pivot (75). Actuation arm (74) pivots about (77) to act on the base of the aerosol canister (8) thereby generating mechanical advantage. A reset arm (78) is connected to end (76) of the plunger at pivot (79) and to

the device housing at (81). When the device is actuated by energising the solenoid the plunger (72) moves downwardly pulling the actuation lever (74) which in turn causes downward movement of the aerosol canister (8) firing the valve. The two pivot points (77, 81) are chosen so that the reset arm (78) moves downwardly during the actuation cycle allowing free movement of the aerosol canister and when the solenoid is de-energised the plunger returns to its rest position causing upward movement of the actuation lever (74) and reset arm (78) moving the aerosol canister (8) to its rest position thereby resetting the valve. The initiation of the valve firing cycle may be conducted as described with reference to the device illustrated in Figure 1.

Referring to Figure 8 the electromechanical means for moving the aerosol canister (8) comprises a solenoid (80), plunger (82) which is connected to cam (84) by a pivoted linkage (86). The cam (84) rotates about (85) to act on an actuation driver (88) which is positioned at the base of the aerosol canister (8). When the solenoid is energised, the plunger moves upwardly and the pivoted linkage (86) causes the cam (84) to rotate pushing the actuation driver (88) downwardly causing movement of the aerosol canister (8) to fire the valve. When the solenoid is de-energised and the plunger returns to its rest position causing rotation of the cam to its rest position the aerosol canister (8) and the actuation driver (88) are moved upwardly under the influence of the internal spring of the aerosol valve.

Figure 9 shows an inhaler (100) with a hinged mouthpiece cover (102) which can be opened to reveal a patient port in the form of a mouthpiece (104). The mouthpiece has attached to it a nozzle block (106) and the mouthpiece/nozzle block are removable for cleaning purposes.

Inserted into the nozzle block is the valve stem (108) of a metered dose inhaler (110). The metered dose inhaler will be referred to as an MDI. The valve stem is prevented from moving down with respect to the nozzle block by a small projection (112) formed as part of the nozzle block. However, there is sufficient space (114) in the nozzle block to allow the remaining parts of the valve (116) to travel downwards during the action of 'firing' the MDI.

The holes (122) in the rear of the device serve as air inlets when the patient inhales on the mouthpiece.

The battery (124) can be accessed through a cover (126) in the back of the device.

Most of the electronic components of the device are on a circuit board (128), this could take the form of a printed circuit board or, to save space, an ASIC for example (i.e. an application specific integrated circuit).

Figure 10 shows a front section of the firing mechanism in more detail. The cam (130) takes the form of a short cylindrical block mounted eccentrically onto the output spindle (132) of a reduction gearbox (134). The cam is mounted within a housing (136) which is free to move up and down with respect to the MDI. The cam and housing are preferably made from similar materials to minimise wear.

A d.c. motor (138), which could be continuous or of the 'stepper' type, is mounted onto the gearbox so that the motor output drives the gears (not shown). The gears are arranged such that the angular velocity of the motor (typically around 13000 rpm) is reduced to give one revolution in approximately 0.2 to 0.5 seconds. Also attached to the gearbox is a micro-switch (140), with its actuator arm (142) resting on the top of the housing (136).

The whole of the firing mechanism is attached to the body of the device (144) by four tension springs (146 to 149) which are attached at one end to a cross-member (150) which bears down on the gearbox and at the other end to the device body.

The operation of the device will now be described.

The patient must first shake the device to mix the contents of the aerosol can and must ensure that the mouthpiece cover is open and the air intakes are clear.

The patient inhales on the mouthpiece, setting up a flow of air into the intakes (122) and through the empty region (152) of the inhaler. The air travels through channels in the nozzle block to either side of the spray outlet and thereafter out through the mouthpiece. (The nozzle block (106) forms a sufficiently good seal with the main body of the device that the preferential path for the air is from the intakes to the mouthpiece).

Whilst still inhaling, the patient must press a switch (not shown) to operate the electro-mechanical firing mechanism. When the switch is depressed the motor is made to turn until the cam has made one complete revolution. As the cam turns, it presses downwards on the housing (136) which in turn presses down on the base of the aerosol can. Since the valve stem cannot move with respect to the nozzle block, which is attached to the body of the device, the net result is that the valve stem is pushed up into the aerosol can thereby firing the MDI and releasing medicament in the normal way.

When the cam returns to the top of its travel the housing contacts the actuator (142) of the micro-switch (140), sending a signal to the electronics to stop the motor.

The diameter of the cam and the point at which it is mounted, are arranged such that at the bottom of its travel the cam has caused the valve to be compressed by

more than the minimum amount necessary to properly fire the MDI. In case the can is arranged such that the valve compression would exceed the maximum permitted travel, the whole of the firing mechanism can lift, against the action of the four springs, to ensure that the can is always able to make a full rotation without stalling. Thus, the strength of the springs must be arranged so that, when acting in unison, they are sufficiently strong to allow the valve to compress normally without extending, but sufficiently weak as to allow the mechanism to lift if the valve 'bottoms out'.

In a preferred variation of this embodiment the device would be made breath activated by incorporating a suitable flow sensor into the space (152). In this case the patient would press a button to turn the electronics on, or a switch could be incorporated in the mouthpiece cover and the electro-mechanical firing mechanism would then be operated automatically as soon as the appropriate triggering flow rate or inhalation parameter was detected. Suitable breath sensors are disclosed in the prior art referred to herein and in our co-pending British Patent Application No. 9023282.8 and the PCT Application of even date based thereon, the disclosures of which are incorporated herein by reference.

CLAIMS

1. An inhalation device for use with a pressurised aerosol canister containing a self-propelling medicament composition equipped with a dispensing valve having a stem movable relative to the canister between a closed position and a dispensing position, the device comprising a housing for supporting said canister and maintaining the valve stem in a fixed position relative to said housing in communication with a patient port, the device additionally comprising electromechanical means for moving said canister thereby actuating the dispensing valve for administration of medicament.

2. An inhalation device as claimed in Claim 1 in which the dispensing valve is a metered dose dispensing valve.

3. An inhalation device as claimed in Claim 1 or Claim 2 in which the electromechanical means for moving the aerosol canister comprises an electric motor or solenoid connected by a driver arrangement to an actuation driver which acts on the aerosol canister or valve ferrule to move the aerosol canister when the electric motor or solenoid is energised.

4. A device as claimed in Claim 3 in which the driver arrangement comprises a screw.

5. A device as claimed in Claim 3 in which the driver arrangement comprises a cam.

6. A device as claimed in any preceding Claim which additionally comprises a reset member which acts on the aerosol canister or valve ferrule, the reset member being driven by an electric motor or solenoid or solenoid spring to return the aerosol canister to a reset position closing the dispensing valve.

7. A device as claimed in Claim 6 in which the electric motor or solenoid or solenoid spring driving the reset member is the electric motor or solenoid or solenoid spring driving the actuation driver.

8. A device as claimed in Claim 6 or Claim 7 comprising control means to actuate the valve reset member after firing the valve.

9. A device as claimed in Claims 6 to 8 which additionally comprises indicating means to prevent valve reset if the canister is not substantially vertical or to warn the patient to hold the canister in a substantially vertical position.

10. A device as claimed in any one of Claims 6 to 9 in which the dispensing valve comprises a spring biasing the valve stem to the closed position, the strength of the spring being selected so that a force of no greater than 15N is required to effect actuation of the device.

11. A device as claimed in any preceding Claim which additionally comprises means for detecting patient inspiration through the patient port and control means for actuating the electromechanical means for moving the aerosol canister in response to detection of patient inspiration.

12. A device as claimed in any preceding Claim which additionally comprises control means to control the dosage frequency by preventing actuation of the electromechanical means for a pre-determined period of time after dispensing a dose or a number of doses of medicament.

13. A device as claimed in any preceding Claim which additionally comprises control means to prevent actuation of the electromechanical means after a predetermined number of doses of medicament have been dispensed from the device.

14. An aerosol device as claimed in any preceding Claim containing said pressurised aerosol canister equipped with a dispensing valve.

15. A method of administering a medicament using an aerosol device as claimed in Claim 14.

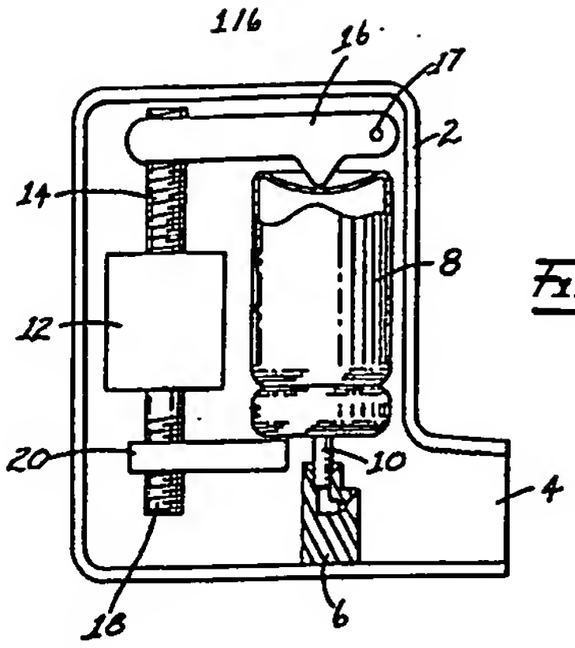

Fig. 1

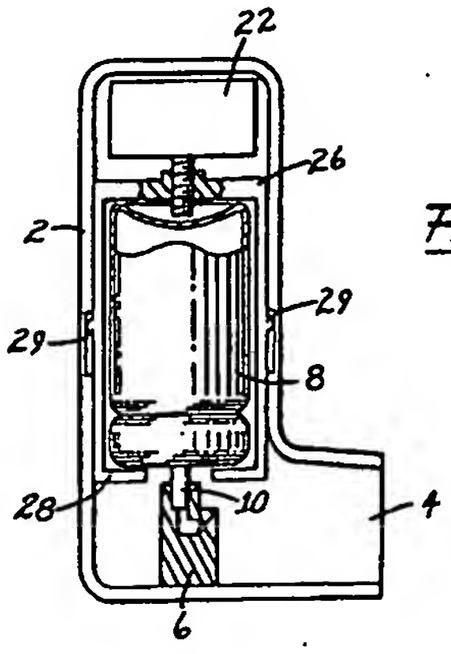

Fig. 2

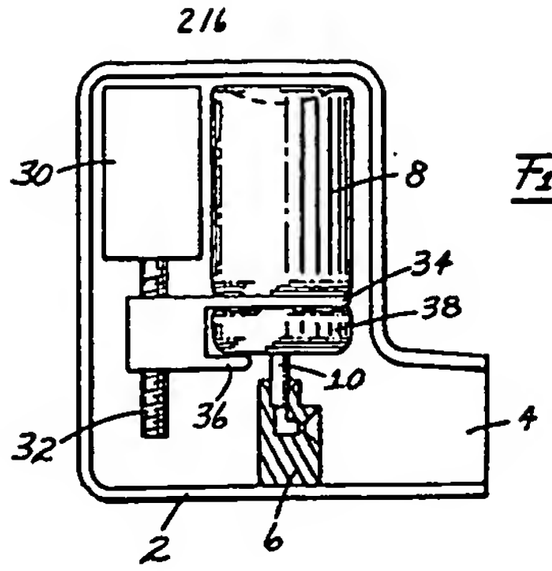

Fig. 3

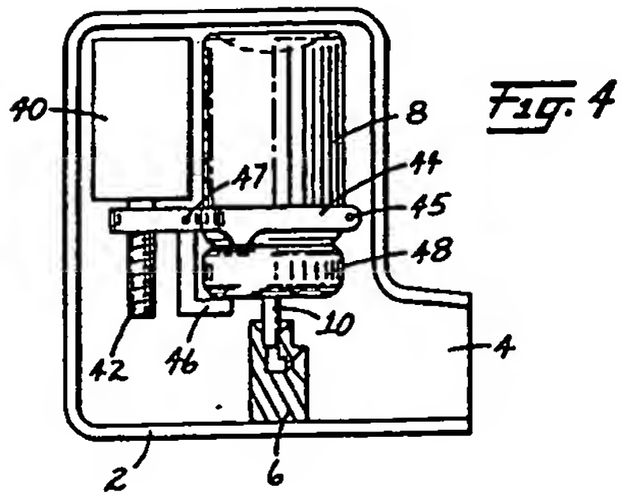

Fig. 4

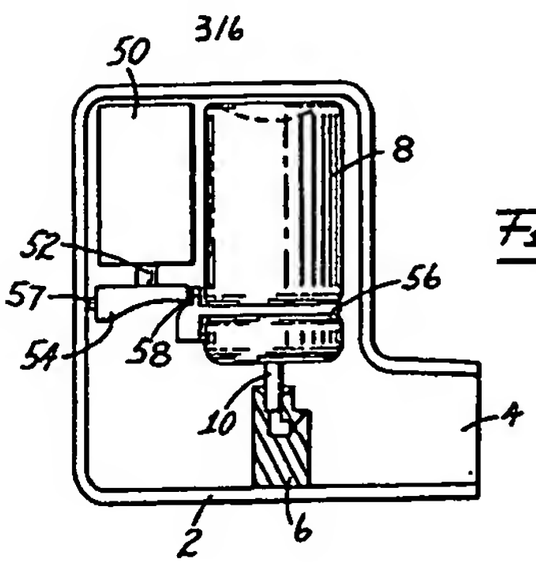

Fig. 5

Fig. 6

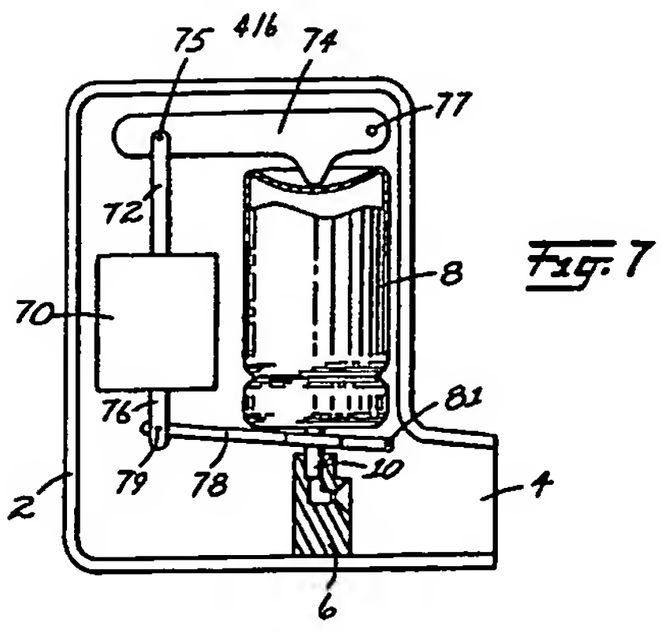

Fig. 7

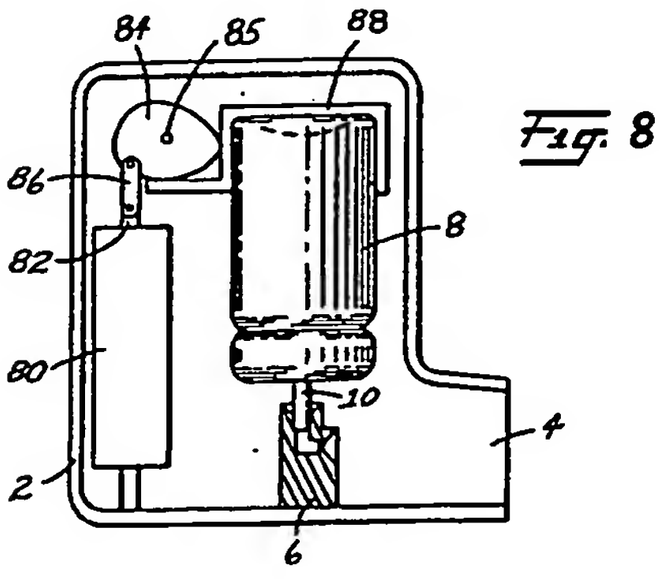

Fig. 8

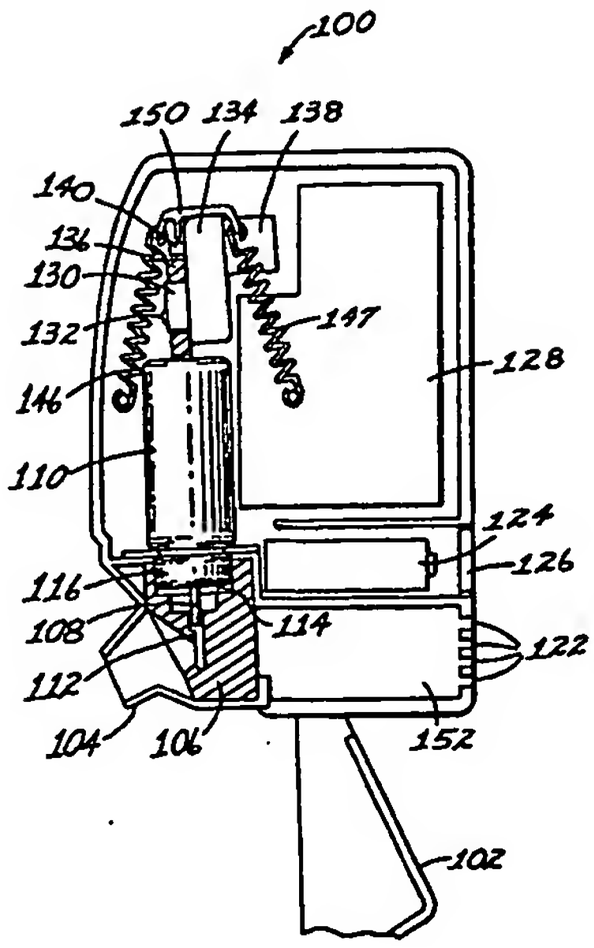

Fig. 9

SUBSTITUTE SHEET

INTERNATIONAL SEARCH REPORT

PCT/GB 91/01869

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M15/00

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category[10]	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
X	DE,C,3 901 963 (J SCHATZ) 9 August 1990 see column 11, line 50 - column 13, line 39 see column 13, line 53 - column 14, line 15 see figures —	1-8,11,14,15

* Special categories of cited documents:[10]
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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
05 FEBRUARY 1992	13.02.92
International Searching Authority: EUROPEAN PATENT OFFICE	Signature of Authorized Officer: VEREECKE A.

Form PCT/ISA/210 (second sheet) (January 1985)

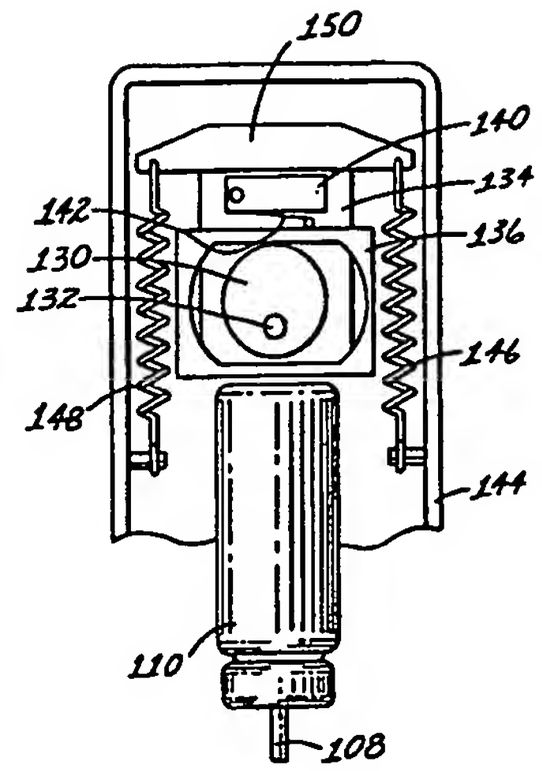

Fig. 10

SUBSTITUTE SHEET

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 9101869 SA 52684

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 05/02/92

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-C-3901963	09-08-90	None	

For more details about this annex : see Official Journal of the European Patent Office, No. 12/91